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DELIVERY DEVICE ~~FOR STIMULATING~~ THE SYMPATHETIC NERVE CHAIN

CROSS-REFERENCE TO RELATED U.S. APPLICATION

The present invention claims priority to U.S. Provisional Application No. 60/353,700, filed February 1, 2002, which is incorporated by reference herein.

FIELD OF THE INVENTION

The present invention relates to a device, assembly, and method of chemically and/or electrically stimulating neural tissue to affect a physiological condition.

BACKGROUND OF THE INVENTION

Electrical stimulation of the brain and spinal cord has been used to affect a select number of physiological conditions such as Parkinson's disease, essential tremors, dystonia, chronic pain, and certain psychiatric disorders. Such therapy is often utilized in a subset of the respective patient population that is unresponsive to other forms of therapy, including traditional pharmacotherapy. There are, however, several other autonomic-related diseases such as cardiac, respiratory, renal diseases, and other diseases associated with autonomic function for which a subset of the patient population is also unresponsive to other forms of treatment.

Stimulation of a sympathetic nerve chain, which extends longitudinally along a side of the vertebral column and which includes a chain of sympathetic ganglia, may be used to alleviate the symptoms of these autonomic-related diseases, even though these diseases are not necessarily related to a dysfunction in the sympathetic ganglia. Because sympathetic ganglia have afferent pathways from the central nervous system and efferent pathways to visceral end organs, modulation of sympathetic ganglia may affect both the end organs and the central nervous system. Methods of electrically and/or chemically stimulating the sympathetic ganglia or the sympathetic nerve chain are described in more detail in the inventor's co-pending application 2002/0116030, which is incorporated by reference herein.

Current electrode devices, such as nerve cuff electrodes, however, are not designed in a manner to efficiently effect stimulation to sympathetic ganglia. Therefore, there is an unmet need for a delivery device that effectively provides stimulation to the sympathetic nerve chain to modulate individual sympathetic ganglion as well as multiple sympathetic ganglia.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will become more fully understood from the detailed description given hereinbelow and the accompanying drawings which are given by way of illustration only, and thus are not limitative of the present invention, and wherein:

FIG. 1 is an inner view of an embodiment of a device according to the present invention.

FIG. 2 is an inner view of an alternative embodiment of a device according to the present invention.

FIG. 3 is an outer view of an alternative embodiment of a device according to the present invention.

FIG. 4 is a perspective view of the device of FIG. 3 according to the present invention in an operative position.

FIG. 5 is an outer perspective view of a component of a device according to the present invention.

FIG. 6 is an outer perspective view of an alternative embodiment of a component of a device according to the present invention.

FIG. 7 is an outer perspective view of an alternative embodiment of a component of a device according to the present invention.

FIG. 8 is an inner view of a device according to the present invention.

FIG. 9 is an outer perspective view of a component of a device according to the present invention.

FIG. 10 is an outer perspective view of a component of a device according to the present invention.

FIG. 11 is a side perspective view of an alternative embodiment of a component of a device according to the present invention.

FIG. 12 is a side view of an alternative embodiment of a component of a device according to the present invention.

FIG. 13 is an inner view of an embodiment of an assembly according to the present invention.

FIG. 14 is a side perspective view of an alternative embodiment of an assembly according to the present invention.

FIG. 15 is a side view of an alternative embodiment of an assembly according to the present invention.

FIG. 16 is a side perspective view of an alternative embodiment of an assembly according to the present invention.

FIG. 17 is a side view of an alternative embodiment of an assembly according to the present invention.

FIG. 18A-B is a top plan view of an embodiment of an engagement mechanism according to the present invention.

FIG. 18C is a perspective view of an alternative embodiment of an engagement mechanism according to the present invention.

FIG. 19 is a side perspective view of an alternative embodiment of an engagement mechanism according to the present invention.

FIG. 20 is a side perspective view of the engagement mechanism of FIG. 19 according to the present invention in a deployed position.

FIG. 21 is a side perspective view of an alternative embodiment of an engagement mechanism according to the present invention.

FIG. 22 is a side view of an alternative embodiment of an engagement mechanism according to the present invention.

FIG. 23 is a side perspective view of an alternative embodiment of an engagement mechanism according to the present invention.

FIG. 24 is a top plan view of an alternative embodiment of an engagement mechanism according to the present invention.

SUMMARY OF THE INVENTION

The present invention relates to a device, assembly, and method for modulating a

a ganglion or ganglia of the nervous system. In a preferred embodiment, the present invention relates to modulating a ganglion or ganglia of the sympathetic nerve chain by chemically and/or electrically stimulating the ganglion or ganglia. One embodiment of the present invention provides a delivery device to stimulate a ganglion including a first series of flexibly connected delivery contacts. A leading one of the first series of flexibly connected delivery contacts is engagably associated with a trailing one of the first series of flexibly connected delivery contacts in an operative position of the delivery device. The delivery device also includes a second series of flexibly connected delivery contacts flexibly connected to the first series of flexibly connected delivery contacts. A leading one of the second series of flexibly connected delivery contacts is engagably associated with a trailing one of the second series of flexibly connected delivery contacts in an operative position of the delivery device. In this embodiment of the present invention, the delivery device maintains a substantially ovoid configuration when in an operative position.

The present invention also provides an assembly for stimulating ganglia and preferably sympathetic ganglia of the sympathetic nerve chain including an axially elongated shaft having an inner surface and an outer surface. The assembly also includes a first probe having a distal end and a proximal end, the distal end of the first probe slidably engagable with the outer surface of the shaft and the proximal end of the first probe insertable in a ganglion. The first probe also includes at least one delivery element disposed thereon. The assembly further includes a second probe having a distal end and a proximal end, the distal end of the second probe slidably engagable with the outer surface of the shaft and the proximal end of the second probe insertable in a ganglion. The second probe also includes at least one delivery element disposed thereon. When the assembly is in an operative position, the distal end of the first probe and the distal end of the second probe are securedly attached to the outer surface of the shaft.

The present invention further provides an assembly for stimulating ganglia, and preferably sympathetic ganglia of the sympathetic nerve chain including an axially elongated shaft having an inner surface and an outer surface. The assembly further includes a first terminal member having a distal end and a proximal end, the distal end of the first terminal member slidably engagable with the outer surface of the shaft and the proximal end of the first terminal member having a generally

concave configuration and adjacently positionable to a ganglion. The first terminal member also includes at least one delivery element disposed thereon. The assembly further includes a second terminal member having a distal end and a proximal end, the distal end of the second terminal member slidably engagable with the outer surface of the shaft and the proximal end of the second terminal member having a generally concave configuration and adjacently positionable to a ganglion. The second terminal member also includes at least one delivery element disposed thereon. In an operative position of the assembly, the distal end of the first terminal member and the distal end of the second terminal member are securedly attached to the outer surface of the shaft.

The present invention moreover provides an assembly for stimulating ganglia and preferably sympathetic ganglia of the sympathetic nerve chain including an axially elongated shaft having an inner surface and an outer surface. The assembly further includes a first delivery structure slidably engagable with the outer surface of the shaft, the first delivery device comprising a first pair of connected clamping members. Each of the first pair of connected clamping members has an outer wall and an inner concave wall and each of the inner concave walls of each of the first pair of connected clamping members has at least one delivery element disposed thereon. The assembly further includes a second delivery structure slidably engagable with the outer surface of the shaft, the second delivery device comprising a second pair of connected clamping members. Each of the second pair of connected clamping members has an outer wall and an inner concave wall and each of the inner concave walls of each of the second pair of connected clamping members has at least one delivery element disposed thereon. When the assembly is in an operative position, the first and second delivery structures are securedly attached to the outer surface of the shaft.

The present invention also provides a method of stimulating a ganglia including encasing a delivery device around at least a portion of a ganglion, wherein the stimulation delivery device comprises at least one delivery element and providing a stimulation signal to the at least one delivery element to stimulate the ganglion.

The present invention further provides a method of stimulating sympathetic ganglia including positioning an axially elongated shaft adjacent to the sympathetic

nerve chain, the shaft having an outer surface. The method further includes slidably engaging a first ganglion stimulator with the outer surface of the shaft, the first ganglion stimulator comprising at least one first delivery element. The method moreover includes placing the first ganglion stimulator adjacent to a first ganglion, securing the first ganglion stimulator to the outer surface of the shaft, and providing a stimulation signal to the at least one first delivery element to stimulate the first ganglion.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to a device, assembly, and method of modulating a ganglia of the nervous system. Non-limiting examples of such ganglia include cranial and extra-cranial ganglia including spenopalatine ganglion, otic ganglion, pterygopalatine ganglion, and ciliary ganglion. In a preferred embodiment, the present invention relates to modulating ganglion or ganglia of the sympathetic nerve chain by chemically and/or electrically stimulating the ganglion or ganglia. Referring to FIG. **1**, one embodiment of the present invention provides a series of delivery contacts **20** that are flexibly connected to each other and that are designed to wrap around an individual ganglion to provide stimulation thereto. A delivery contact **20** generally includes a delivery element **40** (which may be an electrode in the case of electrical stimulation or a drug port in the case of chemical stimulation) disposed atop or co-planar with a pad **30**. In particular, this embodiment provides a delivery device **10** that includes a first series **80** of delivery contacts **20** and a second series **90** of delivery contacts **20**. Each delivery contact **20** of first series **80** is connected to an adjacent delivery contact **20** of the first series **80** by flexible connectors **50** and each delivery contact **20** of the second series **90** is connected to an adjacent delivery contact **20** of the second series **90** by flexible connectors **50**. Furthermore, each delivery contact **20** of the first series **80** is connected to an adjacent delivery contact **20** of the second series **90** by flexible connectors **50**. Within each series **80** and **90**, a leading one **20a** of the delivery contacts **20** of series **80** and **90** is engagably associable with a respective trailing one **20d** of the delivery contacts **20** of series **80** and **90**. In other words, a leading one **20a** of the first series **80** of delivery contacts **20** is engagably associable with a trailing one **20d** of the first series **80** of delivery contacts **20**. Similarly, a leading

one **20a** of the second series **90** of delivery contacts **20** is engagably associable with a trailing one **20d** of the second series **90** of delivery contacts **20**.

Referring to FIG. **2**, in a preferred embodiment, delivery device **10** includes a first series **80** of delivery contacts **20** and a second series **90** of delivery contacts **20** as described above and additionally includes a third series **100** of delivery contacts **20** located between and connected to first series **80** and second series **90**. In particular, each delivery contact **20** of third series **100** is connected to an adjacent delivery contact **20** of third series **100** by flexible connectors **50**. Furthermore, each delivery contact **20** of third series **100** is connected to an adjacent delivery contact **20** of second series **90** by flexible connectors **50** and to an adjacent delivery contact **20** of first series **80** by flexible connectors **50**. A leading one **20a** of the third series **100** of delivery contacts **20** is engagably associable with a trailing one **20d** of third series **100** of delivery contacts **20**. As will be appreciated by one skilled in the art, delivery device **10** can include any number of series of delivery contacts **20** to wrap around a ganglion and provide stimulation thereto.

Referring to FIG. **3**, notwithstanding whether delivery device **10** includes a first and second series **80** and **90** of delivery contacts **20** or a first, second, and third series **80**, **90**, and **100** of delivery contacts **20**, preferably first series **80** is arranged in a concave configuration and second series **90** is arranged in a convex configuration.

Referring to FIG. **4**, when in a operative position, delivery contacts **20a** and delivery contacts **20d** of first series **80**, second series **90**, and third series **100** are engagably associated with each other so that delivery device **10** forms a substantially ovoid configuration to conform to the configuration of a ganglion. In the context of this embodiment of the present invention, by "substantially ovoid configuration" is generally meant all plane sections of delivery device **10** are ellipses or circles in an operative position of device **10**. In the context of this embodiment of the present invention, by "engagably associated" is generally meant that leading delivery contact **20a** and trailing delivery contact **20d** are associated with each other, although not necessarily contacting each other, such that the respective series to which they belong form a secure elliptical or circular configuration in an operative position of device **10**.

Delivery contacts **20a** and **20d** may engagably associate with each other by any means known in the art, such as by any fastening mechanisms including a hook-and eye mechanism, a hook and loop mechanism such as that employed under the tradename VELCRO, buckles, straps, snaps, clamps, staples, and any type of male-female mating members such as nuts and screws, rivets, and the like. For example, as illustrated in FIG. **1**, **3**, and **5**, a free end **60** of flexible connector **50** immediately adjacent to delivery contact **20a** in a direction opposite trailing delivery contact **20d** may have a hook-shape and delivery contact **20d** may define or have attached thereto a loop-shaped structure **70** to engagingly receive free end **60**. Alternatively, as seen is FIG. **6**, delivery contact **20d** may define or have attached thereon buckle **130** through which to receive free end **60** of flexible connector **50**. Alternatively, as seen in FIG **7**, delivery contacts **20a** and **20d** may define or have attached thereon suturing rings **120** through which surgical threading can pass to engagably associate **20a** and **20d** in an operative position of delivery device **10**.

Referring to FIG. **8**, in order to deliver a stimulation signal to each delivery contact **20**, a conduit **150** communicates with each delivery contact **20**. In particular, the distal end of conduit **150** communicates with each delivery contact **20** and the proximal end of conduit **150** is coupled to a stimulation signal controller. In the case of electrical stimulation, each delivery contact **20** includes at least one delivery element **40** that is an electrode, conduit **150** is a conduction cable, and the stimulation signal controller is a signal pulse generator, radio frequency system, or any other generator of electrical energy. In the case of chemical stimulation, each delivery contact **20** includes at least one delivery element **40** that is a drug port, conduit **150** is a catheter, and the stimulation signal controller is a drug pump, or any other structure than can deliver chemical agents to delivery element **40**. In the case of delivering electrical and chemical stimulation, the stimulation signal controller may be both a drug pump and pulse generator. Referring to FIG. **9**, each delivery contact **20** may include a fastening port **220** to securely receive cable **150**.

With respect to details of individual components of delivery device **10**, the particular specifications of delivery device **10** depend on the characteristics of the ganglion being stimulated, which is related to characteristics of the patient, such as age, height, or gender, as well as the type of ganglion desired to be stimulated. With this in mind, each series of delivery contacts **20** may include any number of delivery

contacts **20**, separated by any distance and of any size and configuration, to conform to the configuration of a ganglion in an operative position of device **10**. In a preferred embodiment of device **10**, including a first series **80**, second series **90**, and third series **100**, first series **80** includes four delivery contacts **20**, second series **90** includes four delivery contacts **20**, and third series **100** includes four delivery contacts. Preferably, in a non-operative position, the distance separating adjacent delivery contacts **20** within a series is between about one millimeters and about three millimeter and the distance separating adjacent delivery contacts **20** between series is between about one millimeters to about six millimeters. Preferably, in an operative position, each series of electrical contacts **20** has a diameter between about two millimeter and about ten millimeters with the diameter of the third series **100** being greater than the diameter of the first series **80** and the second series **90**. Although FIG. **1** illustrates each delivery contact **20** being connected to only one other delivery contact **20** in another series, delivery contacts **20** may be also be connected to more than one other delivery contact **20** in another series. For example, as illustrated in FIG. **2**, each delivery contact **20** in first series **80** is connected to two other delivery contacts **20** in second series **90**.

Each delivery contact **20** may have any size or configuration suitable for stimulating a ganglion. Referring to FIG. **10**, in a preferred embodiment delivery contact **20** has a length **L** between about one millimeter and about three millimeters, a height **H** of between about one millimeter and about three millimeter, and a width **W** of between about 0.1 and about 0.2 millimeters. Referring to FIG. **11**, each delivery contact **20** has an inner surface **25**, which faces a ganglion in an operative position of the device and an outer surface **26**. In a preferred embodiment, inner surface **25** of each delivery contact **20** has a concave configuration to conform to the shape of a ganglion. Also in a preferred embodiment, delivery contacts **20** of first series **80** and second series **90** have a trapezoidal configuration, as illustrated in FIG. **1-4**.

Each delivery contact **20** of each series **80**, **90**, and optionally **100** may comprise a single delivery element **40** of any shape or size; a single delivery element of any shape or size that is co-planar with or disposed atop a pad **30**; or more than one delivery element **40** of any shape or size that is co-planar with or disposed atop pad **30**. Delivery elements **40** may be mounted in or on pads **30** through any well

known manufacturing method such as through the use of medical adhesives or forming the delivery elements **40** in pads **30** at the time pads **30** are molded. Referring to FIG. **12**, in a preferred embodiment, delivery element **40** is a pin-shaped structure that can be inserted in a ganglion.

Pads **30** may be of any shape or size and are fabricated of any biocompatible material. For example, pad **30** may be fabricated of any plastic or semi-rigid material including silicone rubber, polyurethane, or other thermoplastics and polymers such as nylon, polytetrafluoroethylene (PTFE) or the like. In a preferred embodiment, pad **30** is fabricated of an insulation material.

Although delivery elements **40** generally serve to deliver stimulation to a ganglion, delivery elements **40** may also detect chemical or electrical activity of a ganglion. For example, first series **80** and second series **90** of delivery contacts **20** may delivery stimulation to a ganglion while third series **90** of delivery contacts **20** act as sensors and detect activity of a ganglion in response to or in preparation of stimulation. Alternatively, alternate ones of first, second, and third series **80**, **90**, and **100** may serve stimulating or sensing functions. Other means of combining stimulation and sensing functions will be readily known to one of skill in the art and such means are within the scope of the present invention.

With respect to connectors **50**, connectors **50** may be manufactured of any elastic, biocompatible, and preferably non-absorbent material such as, for example, polyisoprene, natural rubber, polybutadiene, silicone, a blend of such materials, or the like. Connectors **50** may be attached to delivery contacts **20** by any fastening mechanism such as adhesive bonding, a hook-and eye mechanism, a hook and loop mechanism such as that employed under the tradename VELCRO, buckles, straps, snaps, clamps, staples, and any type of male-female mating members such as nuts and screws, rivets, and the like. In a preferred embodiment, connectors **50** are attached to delivery contacts **20** by a releasable fastening mechanism such that connectors **50** between series can be disconnected and then subsequently re-connected.

The present invention also provides an assembly for stimulating ganglia of the sympathetic nerve chain. In general, this assembly includes an axially elongated shaft that is placed adjacent to a sympathetic nerve chain. The assembly further includes a plurality of ganglion stimulators that can be coupled to the shaft in a

position adjacent to a desired ganglion of the sympathetic nerve chain desired to be stimulated. As additional ganglia are desired to be stimulated, additional ganglion stimulators can be coupled to the shaft. Because the exact location of the sympathetic ganglia desired to be stimulated may vary from patient to patient, such an assembly allows the shaft to be placed adjacent to any sympathetic nerve chain and to slidably position the ganglion stimulators along the longitudinal axis of the shaft, until the ganglion stimulators are adjacent to the desired ganglia. By "ganglion stimulators" is generally meant any device comprising at least one delivery element **40**, which can be either an electrode or drug port, that can provide stimulation to a sympathetic ganglion. Although preferred embodiments of ganglion stimulators are described herein, the present invention contemplates other ganglion stimulators which can achieve the same effect as the preferred embodiments according to the present invention.

In particular, referring to FIG. **13**, one embodiment of an assembly **200** according to the present invention includes a ganglion stimulator that is a delivery device **10** as described in detail above. Assembly **200** further includes an axially elongated shaft **170** having a proximal end **185**, a distal end **195**, an inner surface (not shown) and an outer surface **180** that is slidably engagable with delivery device **10**. Preferably a limit stop **190** is detachably coupled to outer surface **180** of shaft **170** and preferably a lumen extends through shaft **170** to house a conduit to delivery electrical or chemical stimulation to delivery contacts **20** of delivery device **10** (or to delivery elements **40** of any other ganglion stimulator). Shaft **170** may be rigid, semi-rigid, or flexible. Although this embodiment may be used with only one delivery device **10**, in a preferred mode of utilizing assembly **200**, a plurality of delivery devices **10** are employed such that each delivery device **10** is associated with a separate ganglion in the sympathetic nerve chain. The number of delivery devices **10** employed is a function of the number of ganglion desired to be stimulated. In a preferred use, in a loading position of assembly **200**, trailing electrical contact **20d** of series **80**, series **90**, and/or series **100** (in embodiments where series **100** is present) of a first stimulation device **10a** is engaged with outer surface **180** of shaft **170** such that the first delivery device **10a** is capable of slidably engaging outer surface **180** and axially sliding along shaft **170**. Alternatively, another delivery contact **20** (or any other anchoring structure) adjacent to trailing

delivery contact **20d** in a direction opposite leading delivery contact **20a** may be coupled to outer surface **180**. Limit stop **190** prevents first delivery device **10a** from slidably exiting shaft **170** from either proximal end **185** or distal end **195** in a loading position of assembly **200**. After reaching the desired ganglion to be stimulated, assembly **200** assumes an operative position, and first delivery device **10a** is securedly attached to shaft **170** (by securely attached trailing delivery contact **20d** to outer surface **180**) and leading delivery contacts **20a** of series **80**, **90**, and **100** are engagedly associated with respective trailing delivery contacts **20d** of series **80**, **90**, and **100** to wrap around the desired ganglion. If another ganglion is desired to be stimulated, then the same procedure is followed with a second delivery device **10b**. Preferably limit stop **190** is placed inferior or superior to trailing delivery contact **20d** of first delivery device **10a** that is coupled to shaft **180** such that the slidable entry of second delivery device **10b** does not interfere with the position of first delivery device **10a**.

Referring to FIG. **14**, in an alternative embodiment, assembly **200** includes an axially elongated shaft **180** as described above and a ganglion stimulator that is a first probe **210a** having at least one delivery element **40** disposed thereon and having a distal end **220** and a proximal end **230**. In a loading position of assembly **200**, distal end **220** of first probe **210a** is slidably engagable with outer surface **180** of shaft **170** and proximal end **230** of first probe **210a** is insertable in a sympathetic ganglion. Assembly **200** further includes another ganglion stimulator that is a second probe **210b** including at least one delivery element **40** thereon and having a distal end **220** and a proximal end **230**. In a loading position of assembly **200**, distal end **220** of second probe **210b** is also slidably engagable with outer surface **180** of shaft **170** and proximal end **230** is insertable into a ganglion. In an operative position of assembly **200**, distal ends **220** of first probe **210a** and second probe **210b** are secured attached to outer surface **180** of shaft **170** and proximal ends **230** of first probe **210a** and second probe **210b** are inserted into respective ganglia. Probes **210** may define either a single prong, as illustrated in FIG. **14**, or may define dual prongs, **210'** and **210,"** as illustrated in FIG. **15**.

Referring to FIG. **16**, in an alternative embodiment, assembly **200** includes shaft **170** as described above and ganglion stimulators that are delivery structures **240**, each delivery structure **240** slidably engagable with outer surface **180** of shaft

170 in a loading position of assembly 200. In particular, assembly 200 includes a first delivery structure 240a and a second delivery structure 240b, each delivery structure 240 including a pair of pivotably connected clamping members 242 that are designed to encase all or a portion of a sympathetic ganglion. Each clamping member 242 has an outer wall 243 and an inner concave wall 244, which faces a ganglion. Each of the inner concave walls 244 have at least one delivery element 40 disposed thereon. Because each delivery structure 240 is designed to encase all or a portion of a ganglion, each delivery structure 240 is capable of operably moving from an open position wherein each delivery structure 240 is placed around a respective ganglion and a closed or operative position wherein each delivery structure 240 encloses all or a portion of a respective ganglion. Delivery structures 240 may include any means known in the art to effectuate such operable movement, although in a preferred embodiment, clamping members 242 are hingedly connected to each other. Furthermore, although delivery structures 240 may have numerous configurations, such as spherical, conical, or cylindrical, in a preferred embodiment, delivery structures 240 have as ovoid configuration in a closed or operative position such that they conform to the configuration of a sympathetic ganglion. In a further preferred embodiment, each inner wall 244 and outer wall 243 of each clamping member 242 defines a notch 246 such that in a closed or operative position of each delivery structure 240, the post-ganglionic fibers extending from each ganglion are positioned within the aperture created by the mutually confronting notches 246 of each delivery structure 240. In a loading position of assembly 200, first delivery structure 240a and second delivery structure 240b are each slidably engaged with outer surface 180 of shaft 170 and each placed in a open position next to the desired ganglia to be stimulated. Assembly 200 then assumes an operative position and clamping members 242 of each delivery structures 240 are arranged in a closed position such that respective clamping members 242 mutually confront each other and each delivery structure 240 is securedly attached to outer surface 180 of shaft 170.

Referring to FIG. 17, in an alternative embodiment, assembly 200 includes a shaft 170 as described above and ganglion stimulators that are terminal members 280 that are slidably engagable with outer surface 180 of shaft 170 in a loading position of assembly 200. In particular, ganglion stimulators include a first terminal

member **280a** and a second terminal member **280b**, each terminal member **280** having a proximal end **281**, which has a generally concave configuration and includes at least one delivery element **40** disposed thereon, and a distal end **282**. In a loading position of assembly **200**, distal ends **282** are slidably engagable with outer surface **180** of shaft **170** and proximal ends **281** are adjacently positionable to respective ganglia **300**. In an operative position of assembly **200**, distal ends **282** of terminal members **280** are securedly attached to outer surface **180** of shaft **170** and proximal ends **281** are positioned adjacent to the respective ganglia **300**.

Although the above-mentioned embodiments of assembly **200** have been described in relation to sympathetic ganglia of the sympathetic nerve chain, it is understood that such embodiments may also be used in other ganglia in the body, particularly ganglia that are serially arranged.

Notwithstanding the particular embodiment of assembly **200**, each ganglion stimulator is associated with an engagement mechanism that allows each ganglion stimulator to slidably engage outer surface **180** of shaft **170** during a loading position of the respective assembly **200** yet securedly attach to outer surface **180** of shaft **170** during an operative position of respective assembly **200**. Although exemplary engagement mechanisms will now be described in relation to only specific embodiments of assembly **200** for the sake of illustration, it is understood that such engagement mechanisms are generally interchangeable for all the above-described embodiments of assembly **200**. Referring to FIG. **18**, in one embodiment, the engagement mechanism is a clamp **310** that is attached to a ganglion stimulator, which is illustrated in FIG. **18** as being delivery device **10** (only trailing delivery contact **20d** shown). Clamp **310** has a spring-loaded mechanism, for example, that allows clamp **310** to move from an open position, as illustrated in FIG. **18A**, to a closed position, as illustrated in FIG. **18B**. Therefore, when in a loading position of assembly **200** and therefore an open position of clamp **310**, trailing delivery contact **20d** is able to slide along outer surface of shaft **170**. Once the desired ganglion is located, assembly **200** assumes an operative position and clamp **310** is placed in a closed position and attached trailing delivery element **20d** is securely attached to outer surface **180** of shaft **170**, as illustrated in FIG. **18C**. Trailing delivery contact **20d** is then engagably associated with leading delivery

contact **20a**, as described in detail above, so that delivery device **10** is wrapped around the desired ganglion. Although clamp **310** is illustrated as being substantially C-shaped, clamp **310** may take on any configuration that conforms to the shape of outer surface **180** of shaft **170**.

Referring to FIG. **19** and **20**, a ganglion stimulator, which is illustrated as being a probe **210**, has an extension **330** extending from distal end **220** that slidably engages outer surface **180** of shaft **170** during a loading position of assembly **200**. In this embodiment, engagement mechanism is a clip **320** defining a first pair of arms **321** and a second pair of arms **322**. Once the desired ganglion is located, assembly **200** assumes an operative position and clip **320**, as illustrated in FIG. **20**, is positioned about extension **330** such that extension **330** is gripped between first pair of arms **321** and second pair of arms **322** of clip **320**. Although clip **320** is illustrated as being substantially C-shaped and extension **330** is illustrated as being annular, both extension **330** and clip **320** may take on any configuration that conforms to the shape of outer surface **180** of shaft **170**.

Referring to FIG. **21**, in an alternative embodiment, shaft **170** may define slits **350** along the longitudinal axis thereof to engagably receive extension **330** of probe **210**. Alternatively, in embodiments where the ganglion stimulator is sutured in place through the use of surgical threading, shaft **170** may define a series of grooves **360** to retain the surgical threading, as illustrated in FIG. **22**. For example, if the ganglion stimulator is delivery device **10**, then delivery contacts **20a** and **20d** may define or have attached thereon suturing rings **120** as illustrated in FIG. **7**. Surgical threading may then pass through suturing ring **120** of delivery contact **20a**, wrap around the ganglion, enter in and be secured by a groove **360** and pass through suturing ring **120** of delivery contact **260**. The surgical threading may then be fastened to secure delivery device **10** around the ganglion. Referring to FIG. **23**, shaft **170** may alternatively define a series of apertures **370** along the longitudinal axis thereof and extension **330** of probe **210** may also define a through-hole **375** to receive a securement pin **376**. In a loading position of assembly **200**, probe **210** is slidably engaged with outer surface **180** of shaft **170** and once reaching the location of the desired ganglion, assembly **200** assumes an operative position and through-hole **375** is brought in registration with the respective aperture **370** of shaft **170** to

align probe **210** with the desired ganglion. Securement pin **376** is then inserted into through-hole **375** and respective aperture **370** to secure probe **210** to shaft **170**.

Referring to FIG. **24**, in an alternative embodiment, engagement mechanism of assembly **200** is a clasp **380** and ganglion stimulator is a delivery structure **240**. Clasp **380** has a receiving portion **381** defining an opening **383** and a moveable portion **382** that is slidably insertable through opening **383** into receiving portion **381**. In an open position of delivery structure **240**, moveable portion **382** rests within receiving portion **381** and as clamping members **242** are brought in mutual confrontation to surround a ganglion, moveable portion **382** is urged through receiving portion **381** towards opening **383**. Based on the diameter of delivery structure **240**, the length of moveable portion **382** is such that moveable portion **382** does not exit opening **383** when delivery structure **240** is in a fully closed position. In a loading position of assembly **200**, clasp **380** is slidably engaged with outer surface **180** of shaft **170**. Once the desired ganglion to be stimulated is reached, clamping members **242** are moved into a closed and operative position and moving portion **382** of clasp **380** is urged towards opening **383**. Clasp **380** is then secured to shaft **170** by a securement pin **376**, or a clip **320** or any other suitable engagement mechanism described above.

The present invention also provides a method of stimulating sympathetic ganglia of the sympathetic nerve chain by positioning shaft **170** adjacent to the sympathetic nerve chain, slidably engaging a first ganglion stimulator with outer surface **180** of shaft **170**, the first ganglion stimulator comprising at least one first delivery element **40**. The method moreover includes placing the first ganglion stimulator adjacent to a first ganglion, securing the first ganglion stimulator to outer surface **180** of shaft **170**, and providing a stimulation signal to the at least one first delivery element **40** to stimulate the first ganglion. The method may further include slidably engaging a second ganglion stimulator with outer surface **180** of shaft **170**, the second ganglion stimulator comprising at least one second delivery element **40**, placing the second ganglion stimulator adjacent to a second ganglion, securing the second ganglion stimulator to outer surface **180** of shaft **170** and providing a stimulation signal to the at least one second delivery element **40** to stimulate the second ganglion. Although the above-described method has been described with respect to sympathetic ganglia of the sympathetic nerve chain, it is understood that

such method may be used with other ganglia as well, particularly ganglia that are serially arranged

Notwithstanding the precise nature of the engagement mechanism of assembly **200**, in a preferred embodiment, when delivery elements **40** are electrodes, delivery elements **40** of the respective ganglion stimulators are adjustable powerable. For example, the pulsing parameters of delivery elements **40** may be adjusted to initiate, stop, increase, or decrease the pole combinations, energy, amplitude, pulse width, waveform shape, frequency, and/or voltage or any other pulsing parameter known to one of skill in the art to adjust the degree of stimulation delivered thereby. In a preferred embodiment, each delivery element **40** of each ganglion stimulator is selectively powerable such that the pulsing parameters of a delivery element **40** can be adjusted independent of the pulsing parameters of another delivery element **40** of either the same ganglion stimulator or a different ganglion stimulator. In the case of stimulating serially-arranged ganglia such as the ganglia of the sympathetic nerve chain, such selective powerability permits different ganglia of the sympathetic nerve chain to receive different characteristics of stimulation depending on the particular stimulation effects desired to be imparted on the specific ganglion. Methods of selectively powering and steering electrical stimulation are described in U.S. Patent No. 5,713,922, which is incorporated by reference herein.

A delivery device **10** or stimulation delivery assembly **200** according to the present invention may include or be incorporated with other components useful in identifying, monitoring, or affecting a specific ganglion or ganglia or a particular physiological condition associated with the specific ganglion or ganglia. For example, such a system could include a component for lesioning and temperature monitoring, and/or a component that has a fiberoptic monitor which allows telemetric intracranial monitoring capabilities, and/or a microelectrode recording component, and/or a sensing component to incorporate a feedback mechanism to assist in determining whether the delivery contacts **20** should be adjusted or relocated to a different ganglion. If an assembly **200** according to the present invention is utilized, the above-mentioned components could be incorporated in shaft **180**.

With respect to a sensing component according to the present invention, a sensor can be used with a closed-loop feedback system in order to automatically determine the level of stimulation necessary to provide the desired therapy. The sensor may be implanted into a portion of a patient's body suitable for detecting characteristics, symptoms or attributes of the condition or disorder being treated such as electrical brain activity, cerebral blood flow, and/or vital signs or other chemical and electrical activity of the body. Sensors suitable for use in a system according to the present invention include, for example, those disclosed in U.S. Patent No. 5,711,316, which is incorporated by reference herein.

Furthermore, a stimulation device **10** or assembly **200** according to the present invention may also include or be incorporated with a navigation system that provides the exact position/orientation of device **10** or assembly **200** within the nervous system after device **10** or assembly **200** has been deployed. Preferably, when assembly **200** is utilized such a navigation system is incorporated in shaft **170**. For example, if device **10** or assembly **200** has a circular cross-section, the navigation system would provide the compass direction (i.e. degree) device **10** or assembly **200** is positioned relative to a reference point in the nervous system therefore assisting in the determination of where to place device **10** or the ganglion stimulators of assembly **200**. Preferably the navigation system would incorporate some type of marker that is integral with device **10** or assembly **200** that would show up under computer tomography (CT) or magnetic resonance imaging (MRI) scanning techniques. According, the scans could be printed and fed into a computer having navigational software and a three-dimensional atlas of the patient's sympathetic nerve chain to model approximately where all the devices **10** or ganglion stimulators of assemblies **200** are positioned. The software may then be capable of providing instructions on where best to position device **10** or the ganglion stimulators of assembly **200** or which delivery elements **40** to activate.

Although the invention has been described with reference to the preferred embodiments, it will be apparent to one skilled in the art that variations and modifications are contemplated within the spirit and scope of the invention. The drawings and description of the preferred embodiments are made by way of example rather than to limit the scope of the invention, and it is intended to cover within the spirit and scope of the invention all such changes and modifications.